IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION

Case No. 1:15-cv-07488-CM (RWL)

MEMORANDUM IN SUPPORT OF FOREST'S MOTION *IN LIMINE* 2 TO EXCLUDE GENERAL STATISTICAL EVIDENCE OF OUTCOMES IN UNRELATED PHARMACEUTICAL PATENT LITIGATIONS

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An important question in this antitrust case concerns whether U.S. Patent No. 5,061,703 (the "'703 patent"), specifically, would have been upheld as valid in the underlying patent litigation (the "'703 Patent Litigation"). To argue in favor of the invalidity of the '703 patent, DPPs apparently will seek to introduce general evidence of average win rates for brands and generics from a wide swath of patent litigations ***wholly unrelated*** to the '703 Patent Litigation. *See* Ex. 1, Expert Rep. of George W. Johnston, Esq. ("Johnston Rep.") at ¶¶ 73-86 (speculating as to "Statistical Likelihood of Success In a Hatch-Waxman Case – In General") and ¶¶ 87-109 (comparing Hatch-Waxman "win rates" discussed in academic articles for hundreds of Hatch-Waxman cases and dozens of parties spanning the period 2002-2013); ECF No. 713, Mem. of Law in Opp. to Forest's Motion for Leave to Suppl. its Expert Reps. at 15 (stating that "[b]ased on a study by RBC Capital, [Dr. Reddy's Laboratories] has an abysmal 28% success rate in Hatch-Waxman litigations" and citing to an RBC Capital Markets Industry Comment showing that **Mylan**, not Dr. Reddy's Laboratories, had a 28% success rate in Hatch-Waxman litigations from 2000-2009).

Generalized evidence of the outcomes for brand and generic companies in ***all*** Hatch-Waxman litigations throughout the United States has no bearing on the merits of the specific patent case brought by Forest against Mylan and the other generic manufacturers. This is particularly true here, where the validity of the '703 patent was a key issue that would impact the outcome of the '703 Patent Litigation, and it is "axiomatic" that a patent is "born valid" and remains so until a challenger proves otherwise by clear and convincing evidence. *Upjohn Co. v. Medtron Labs., Inc.*, 751 F. Supp. 416, 423 (S.D.N.Y. 1990) (upholding patent validity after review of the merits of a challenger's case and enjoining patent defendants); *see also* 35 U.S.C. § 282 ("A patent shall be presumed valid. . . . The burden of establishing invalidity of a patent or

any claim thereof shall rest on the party asserting such invalidity."). For these reasons, the Court should grant Forest's motion *in limine* and exclude any evidence or testimony regarding generalized evidence of the outcomes of unrelated patent litigations or statistical analyses of such outcomes or litigations.

ARGUMENT

I. Generalized Evidence of the Outcomes for Brand and Generic Companies in Other Hatch-Waxman Litigations Is Irrelevant to the Merits of the '703 Patent Litigation, the Probative Value of this Evidence Is Substantially Outweighed by the Risk of Unfair Prejudice to Forest, and this Evidence Should Be Barred Under Rule 403

Courts must decide patent infringement and validity on the respective merits of each issue, and generalized evidence regarding patent litigation outcomes is not relevant to whether a ***specific*** patent is infringed or should be upheld as valid. *Carucel Invs., Ltd. P'ship v. Novatel Wireless, Inc.*, No. 16-cv-00118-H-KSC, 2017 U.S. Dist. LEXIS 50855, at *58-60 (S.D. Cal. Apr. 3, 2017) (granting motion *in limine* because a "publication that sets forth noncontroversial statistics regarding patent litigation" provides only "general statistics that are untethered to the facts in this case and, therefore, should be excluded"); *Mentor Graphics Corp. v. Quickturn Design Sys., Inc.*, Nos. 00-cv-01030, 99-cv-05464, 00-cv-03291, 02-cv-01426, 2003 U.S. Dist. LEXIS 16195, at *9-10 (N.D. Cal. July 29, 2003) ("[T]he Federal Circuit has made it clear that infringement and invalidity should both be decided on the merits when raised . . . .") (relying on *Pandrol USA, LP v. Airboss Ry. Prods.* 320 F.3d 1354, 1365 (Fed. Cir. 2003); *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1583 (Fed. Cir. 1983)).

What DPPs seek to do here is especially concerning, as it appears to be an attempt to make an end-run around the presumption of patent validity and the high evidentiary bar attendant in mounting an invalidity defense ***on the merits by clear and convincing evidence***. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983) ("[T]he party asserting

invalidity not only has the procedural burden of proceeding first and establishing a prima-facie case, but the burden of persuasion on the merits remains with that party until final decision"); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359-60 (Fed. Cir. 2007) ("Since we must presume a patent valid, the patent challenger bears the burden of proving the factual elements of invalidity by clear and convincing evidence."). The evidence of generalized outcomes DPPs seek to introduce simply has no bearing on the specific merits of the '703 Patent Litigation, or the motivations of the parties actually involved in that litigation, and therefore is not relevant to the patent merits at issue here. *See*, *e.g.*, Ex. 1, Johnston Rep. at ¶ 88, Table 1 (purporting to show "Win Rates" for 2002-2004 for over 262 "dispositive cases," years before the '703 Patent Litigation even took place); ¶ 94, Table 2-4 (purporting to show "Patent Litigation Results per Drug Product" for 40 "NDAs," without reference to specific cases or years); ¶ 98, Exhibit 4 (purporting to show outcomes for the 15 "Best Generic Challengers" with no explanation for why a particular outcome occurred); *see also* ECF No. 713 Mem. of Law in Opp. to Forest's Motion for Leave to Supplement Its Expert Reps. at 15 (same).

Indeed, while courts have long been skeptical of the admissibility of evidence relating to prior litigation between the ***same*** parties, here, the evidence DPPs seek to introduce does not even specifically relate to Forest, Mylan, or even the other settling generic manufacturers. *See TVT Records v. Island Def Jam Music Grp.*, 250 F. Supp. 2d 341, 345-46 (S.D.N.Y. 2003) (evidence of prior litigation conduct for "purpose of portraying TVT as perpetually litigious will not be permitted, insofar as such evidence may be irrelevant, unduly prejudicial and not probative and distracting to the jury"); *see also Plymack v. Copley Pharm.*, 93-cv-02655 (KMW), 1997 U.S. Dist. LEXIS 3759, at *10-12 (S.D.N.Y. Mar. 13, 1997) (granting motion *in limine* and excluding all evidence of prior litigation as irrelevant and unfairly prejudicial).

DPPs' evidence purports to track the performance of all brand and generic manufacturers, which is far more attenuated than the evidence excluded in *TVT Records* and *Copley*. The probative value of evidence of ***other*** parties' success or failure in unknown other litigations to establish the likely outcome of the '703 Patent Litigation is substantially outweighed by the risk of unfair prejudice to Forest and should be excluded under Rule 403.

DPPs cannot provide any explanation for why evidence of brand and generic companies' performance in patent litigations, in general, has any relevance to the analysis outlined by *FTC v. Actavis*. 570 U.S. 136, 158 (2013) (analyzing whether an accused payment can be used as "a workable surrogate for a patent's weakness" on the merits of the specific patent at issue). DPPs cannot show that the merits of these unrelated Hatch-Waxman cases bear any resemblance to the merits of the '703 Patent Litigation. Neither do DPPs seek to introduce such evidence as admissions by any party actually involved in this lawsuit or even as an exception to the bar on hearsay. *See Park W. Radiology v. CareCore Nat'l LLC*, 675 F. Supp. 2d 314, 329 (S.D.N.Y. 2009) (persuaded that pleadings by same party in prior litigations constituted inadmissible hearsay, and that probative value of references was substantially outweighed by the risk of unfair prejudice, confusion of the issues, misleading the jury, and waste of time). DPPs' only purpose in introducing this evidence is to confuse the issues before the Court and the jury, namely, the validity of the '703 Patent on the merits, for which Forest is entitled to a presumption of validity.

CONCLUSION

For these reasons, Forest respectfully requests that this Court preclude DPPs from introducing at trial any evidence regarding unrelated patent litigations, generalizations regarding the outcomes of these unrelated cases, or any purported statistical analyses of such litigation.

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Respectfully submitted,

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